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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
San Francisco District

1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 29, 1998

Our Reference: 2918275

Eugene Bugatto, President
Robert Bugatto Enterprises, Inc. dba The Tides Wharf
P.O. Box 2028
San Francisco, California 94126

WARNING LETTER

Dear Mr. Bugatto:

On August 20 and 24, 1998, Investigators Darla Bracy and Thomas Latt of the U.S. Food and Drug Administration (FDA) conducted an inspection of your seafood processing facility located at 835 Highway 1, Bodega Bay, California. The inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110). The inspection documented deviations which constitute violations of the Federal Food, Drug, and Cosmetic Act, and related regulations for seafood processing and good manufacturing practices.

In conjunction with the inspection, a sample of vacuum packaged smoked albacore tuna was collected and analyzed by FDA. Results of the analysis by the FDA laboratory showed that the smoked albacore tuna has an average water phase salt of 3.06 percent and 3.12 percent, by original and check analysis, respectively. To control *Clostridium botulinum* toxin formation in a vacuum packaged smoked fish or smoke-flavored fish, the guideline for water phase salt is 3.5 percent or higher. Water phase salt below 3.5 percent would not provide a preventive control for *C. botulinum* toxin formation in a refrigerated, vacuum packaged, smoked fish or smoke-flavored fish product. The lot of hot smoked albacore tuna presents a potentially hazardous condition in that refrigeration alone is not adequate to inhibit toxin formation by *C. botulinum*. Although your smoked albacore is kept frozen while in your control, it is distributed in a refrigerated vehicle and storage instructions for the consumer are to keep the

product refrigerated. This concerns our agency because proper refrigeration temperatures are not always maintained at the retail and consumer levels.

During the inspection, the FDA investigators also observed shortcomings in your HACCP system, that upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. At the conclusion of the inspection, Investigator Bracy provided Mr. Antonio Delima, Manager, with a copy of the Domestic Seafood HACCP Report (form FDA 3501) and the Inspectional Observations (form FDA 483) and discussed her findings with him. Briefly, these deviations are as follows:

1. Failure to develop and implement a written HACCP plan to address potential hazards associated with fresh, refrigerated tuna and mahimahi received and processed by your firm (21 CFR 123.6(b)).

2. Failure to include in your HACCP plan for hot smoked fish, measures to control histamine formation because of time/temperature abuse during the thawing, butchering, and brining of tuna (21 CFR 123.6(b)). During the inspection, the FDA investigators observed the internal temperature of tuna steaks held at ambient temperature in a wheeled tote, prior to brining, ranged from 41.7°F to 52.3°F. Exposure of scombroid fish species such as tuna at temperatures above 40°F for four hours cumulatively, could result in unsafe levels of histamines.

3. Failure to include in each of your HACCP plans for cold smoked fish and hot smoked fish, process controls to address the hazard of *Clostridium botulinum* toxin formation (21 CFR 123.16). Specifically, at the brining and the smoking/cooking critical control points (CCPs), there are no verification records to show that the critical limits and monitoring procedures specified in the HACCP plans are adequate to control formation of toxin by *C. botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

4. Failure to maintain records to document monitoring of the critical control points identified in your HACCP plans (21 CFR 123.6(c)(7)). Specifically, on July 3, 1998, the cooler temperature was not recorded during the cooling of tuna after the hot smoking step. Also, for the period June 22 to June 28, 1998, your firm failed to record the cooler temperatures on these days.

5. Failure to include in the HACCP plans for smoked fish adequate corrective actions to address deviations from the critical limits (21 CFR 123.7(b)). Specifically, at the brining, smoking/drying, and the packing/labeling CCPs, the predetermined corrective actions did not provide a plan to ensure that the cause of the deviation is corrected.

6. Failure to establish in your HACCP plan for cooked crab the appropriate critical limit at the receiving CCP (21 CFR 123.6(c)(3)). The critical limit established for receiving

refrigerated ready-to-eat cooked crab failed to address product internal temperature that will prevent pathogen growth and toxin formation.

7. Failure to establish adequate verification procedures in your HACCP plan for crab to address the hazard of pathogen growth and toxin formation as a result of time/temperature abuse during the cooling step (21 CFR 123.8).

8. Failure to maintain sanitation monitoring records to document the safety of water that comes in contact with food or food contact surfaces, or is used in the manufacture of ice (21 CFR 123.11(c)).

9. Failure to monitor your plant sanitation in accordance with 21 CFR 123.11(b) and (c).

10. The HACCP plan must be changed under "Method of Storage and Distribution" to indicate that the product is not frozen until use.

Objectionable conditions were also observed by FDA during the inspection which constitute violations of the good manufacturing practice (GMP) requirements and provide evidence of inadequate sanitation monitoring. Briefly, these are as follows:

(a) Seagulls were observed entering the plant's processing room at least twelve times through the roll-up door, during processing; at least three times, seagulls were about thirty feet into the processing room;

(b) The presence of flying insects in the firm's processing room during fish operations;

(c) Raw tuna chunks held in unsanitized wheeled totes. These totes were previously stored outside the plant uncovered and seagulls were observed about thirty feet away from them.

(d) Crab cooking operations performed outside of the facility exposing the food to potential contamination. Bird excreta were observed on the crab cooker lids and the fish washer lid. About ten seagulls were observed by the FDA to be approximately thirty feet away from the crab cooker and the fish washer.

(e) Employee routinely storing shovels without adequate washing and sanitizing. These shovels are used for picking up fish debris from the processing room floor and from outside of the roll-up door and also being used, without sanitizing, to pick up ice that is used in raw fish.

(f) Employees wearing jewelry while butchering tuna; one employee was observed wearing a dirty cotton glove while handling tuna chunks.

Foods processed in your facility under these conditions are adulterated within the meaning of Section 402(a)(4) of the Act in that they were prepared, packed, or held under insanitary conditions whereby they may become contaminated with filth, or whereby they may be rendered injurious to health. Adulterated foods are subject to seizure as authorized by Section 304 of the Act. Adulteration of food while held for sale after receipt in interstate commerce, is prohibited by Section 301(k).

Similar HACCP deviations were observed during the previous inspection on May 13, 14, and 26, 1998. Following the May 1998 inspection, the FDA investigators presented a written list of inspectional observations and discussed the findings with Mr. Delima and Mr. Mark Mehnert, Supervisor. These HACCP deviations were also reported to you by correspondence from this office on July 10, 1998. We are concerned that you have not corrected most of the HACCP deviations cited in our previous letter although Mr. Delima and Mr. Mehnert told the investigators that they would correct them. We acknowledge, however, that your firm has begun maintaining sanitation monitoring records, shellfish receiving records, and has been performing weekly monitoring record reviews.

You must immediately take appropriate steps to correct the violations at your facility. Failure to correct the violations may result in legal sanctions such as seizure and/or injunction without further notice.

Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Please direct your response to Ms. Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; FAX: 510-337-6707).

Sincerely,

Wayne L. Lavendel
Acting District Director

Patricia C. Ziobro
District Director
San Francisco District

cc: Antonio M. Delima, Manager
The Tides Wharf
P.O. Box 518
Bodega Bay, CA 94923